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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ELI LILLY AND COMPANY,

Plaintiff,

vs.

EMPOWER CLINIC SERVICES, LLC d/b/a EMPOWER PHARMACY, EMPOWER CLINIC SERVICES NEW JERSEY, LLC d/b/a EMPOWER PHARMA,

Defendants.

Civil Action No. 2:25-cv-02183 (MEF) (MAH)

Electronically Filed

To: Hon. Michael E. Farbiarz, U.S.D.J.

Return Date: To Be Set by the Court

Oral Argument Requested

DEFENDANTS' EMPOWER CLINIC SERVICES, L.L.C. D/B/A EMPOWER PHARMACY AND EMPOWER CLINIC SERVICES NEW JERSEY, LLC D/B/A EMPOWER PHARMA MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM

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Pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, Defendants Empower Clinic Services, L.L.C. d/b/a Empower Pharmacy and Empower Clinic Services New Jersey, LLC d/b/a Empower Pharma (collectively "Empower"), through their undersigned counsel, submits their Motion to Dismiss Plaintiff Eli Lilly and Company's Complaint ("Lilly" or "Plaintiff") for Failure to State a Claim and Memorandum in Support respectfully requesting that this Court dismiss all claims that Plaintiff asserts against Empower. In support of its Motion, Empower states as follows:

I. PRELIMINARY STATEMENT

This case is not about Empower—this is merely one in a series of cases Lilly has filed as part of a national strategy to drive compounders like Empower from the market for compounding with tirzepatide.[1] Under the guise of claiming "false advertising" and "patient safety" concerns" Lilly is waging an anti-competitive campaign across the country, attempting to regain from compounders the market control that Lilly feels it lost during a lengthy drug shortage caused by Lilly's inability to meet patient demand.

For nearly two years, the Food and Drug Administration ("FDA") consistently determined Lilly was unable to meet demand for its tirzepatide-based medications (Zepbound® and Mounjaro®). Lilly's failure to adequately scale up its manufacturing capabilities resulted in a lengthy drug shortage. During Lilly's drug shortage, compounders like Empower dutifully performed their lawful, congressionally-designated roles under the federal Food, Drug, and Cosmetic Act ("FDCA")—making compounded versions of the Plaintiff's medications to avoid leaving patients without access to critical medications. In other words, far from placing patients in danger, compounders like Empower assisted patients that Lilly had left behind. After all, a drug that is unavailable cannot treat anyone—no matter how

[1] To date, Lilly has filed 33 lawsuits across the country relating to compounding with tirzepatide.

remarkable or effective that approved drug is.

Now that FDA has determined Lilly can make enough of its tirzepatide-based medications to meet patient demand, Lilly ostensibly comes to this Court to challenge what Empower is ***saying*** about its compounded tirzepatide-based drugs. But Lilly's real objection is with what Empower is ***doing***: using tirzepatide in compounding at all. Lilly's position that this matter is about "false and misleading advertising" is a ruse and belied by its prayer for relief—wherein Lilly seeks to permanently enjoin Empower from "distributing, dispensing, selling, or otherwise making available to consumers" Empower's Tirzepatide orally disintegrating tables ("ODT") and Empower's tirzepatide/niacinamide injection.

But there is nothing wrong with what Empower is doing—Empower is using tirzepatide to compound medications when prescribed by a physician as permitted by the FDCA. The FDCA—not Lilly—dictates the parameters for how, why, when, and where to use active pharmaceutical ingredients, including tirzepatide, in compounding. Congress directs FDA—and FDA alone—to interpret and police the FDCA. Lilly knows this, because Lilly has been told by several federal district court judges that Lilly cannot enforce the FDCA to police compounders using tirzepatide in compounded drugs.[2]

So, Lilly tries to plead around the FDCA by posing as a deceived "New Jersey consumer" who has been duped by Empower's allegedly false and misleading advertising. But Lilly is a drug manufacturer—not a New Jersey consumer. Therefore, Lilly's New Jersey Consumer Fraud Act

[2] *Eli Lilly & Co. v. Wells Pharmacy Network, LLC*, No. 23-576, 2024 U.S. Dist. LEXIS 70524, *8 (M.D. Fla. Feb. 5, 2024) ("Lilly does not allege any claim based on Florida tort law. Instead, Lilly's … claim is based on a violation of the [FDCA], and is therefore preempted."); *Eli Lilly & Co. v. RXCompoundStore.com, LLC*, No. 23-23586, 2024 U.S. Dist. LEXIS 65172, *16–17 (S.D. Fla. Apr. 9, 2024) (relying in part on *Wells Pharmacy Network* and holding that plaintiff's FDUTPA claim was a back door attempt to privately enforce the FDCA and is therefore preempted).

("NJCFA") claims (Counts I and II) fail for lack of standing.

Moreover, Lilly's attempt to plead a Lanham Act Claim (Count III) for false and misleading advertising also fails. Empower can certainly tell the marketplace what it is doing—Empower *can* cite to studies about the active ingredient tirzepatide for its compounded medications containing tirzepatide, Empower *can* call its compounded medications "personalized" because they are compounded within the FDCA's parameters for personalized compounded drugs, and Empower *can* say that it currently complies with federal and state regulations. Empower's statements are literally true, non-actionable opinion and puffery, and/or Lilly's Lanham Act claims are precluded by the FDCA. Lanham Act precedent empowers this Court to make each of these legal determinations at the motion to dismiss stage.

For all of these reasons, Lilly's complaint should be dismissed pursuant to Rule 12(b)(6).

II. FACTUAL BACKGROUND

Lilly manufactures two FDA-approved drug products containing tirzepatide as the main macromolecule and active pharmaceutical ingredient ("API"): Zepbound® and Mounjaro®. Complaint ¶ 28, *Lilly v. Empower*, No. 2:25-CV-02183 (D.N.J. Apr. 1, 2025). Empower operates two separate outsourcing facilities, one in Texas and one in New Jersey, both registered with FDA under 21 U.S.C. § 353b ("Section 503B"). Empower also operates a separate, Texas-based pharmacy that engages in compounding under 21 U.S.C. § 353a ("Section 503A") and state law.[3] Among Empower's various medications, Empower's Texas-based pharmacy is compounding tirzepatide in oral form and tirzepatide/niacinamide pursuant to physicians' determinations that the compounded medications are necessary for patient treatment.

When Lilly's drug shortage ended, Lilly expected all compounders to immediately cease

[3] *See infra* for a more fulsome discussion of compounding and the laws governing it.

compounding with tirzepatide, the active pharmaceutical ingredient in Lilly's drugs. Thus, Empower's continued compounding with tirzepatide—which is permitted by the FDCA—is what has garnered Lilly's ire. Compl. ¶ 2. Lilly's complaint is grounded in a fundamental objection to the federal and state regulations governing compounded medications as a legitimate treatment option for physicians to choose for patient care. Compl. ¶ 1. Compounding is not some illegitimate, counterfeit practice of making knock-off drugs, as Plaintiff repeatedly alleges. Compl. ¶¶ 31-37. And, contrary to Lilly's repeated refrain, the lawful compounding of drugs that are statutorily exempt from FDA approval does not render them "knockoffs." As set forth below, federal law explicitly authorizes compounding with tirzepatide when a physician determines that Lilly's manufactured drug is not appropriate to treat patients.

A. Congress Codifies Compounding Into the FDCA.

In 1938, Congress enacted the FDCA to regulate commercial drug manufacturing. *See Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 388 (5th Cir. 2008). Under the FDCA, drugs manufactured, distributed, and marketed in the United States are subject to FDA's approval process, providing that "no person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed [with FDA] … is effective with respect to such drug." *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 361 (2002) (quoting 21 U.S.C. § 355(a)). In turn, "[t]he FDA may approve a [new drug application] only where there is (a) sufficient information to determine the drug is safe to use as proposed, and (b) substantial evidence the drug will have the effect it is purported to have when used as proposed," as established through clinical trials. *Frater v. Hemispherx Biopharma, Inc.*, 996 F. Supp. 2d 335, 338 (E.D. Pa. 2014) (quoting 21 U.S.C. § 355(d)(4)–(5)).

When first enacted, the FDCA did not address drug compounding, which is a traditional component of the practice of pharmacy involving "a process by which a pharmacist or doctor

combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient." *Western States*, 535 U.S. at 360–61. Compounding occurs when a physician determines a manufactured drug is inappropriate or unavailable to treat a patient. *Id*. at 361. For many years, the historic practice of pharmacy compounding remained only regulated by the states. *Id*. at 362.

As compounding expanded, however, "FDA grew concerned that some pharmacies were turning into manufacturers of new drugs without going through the FDA-approval process for manufacturing." *Nexus Pharms., Inc. v. Cent. Admixture Pharm. Servs.*, 48 F.4th 1040, 1042 (9th Cir. 2022). In response to FDA's concerns, Congress promulgated the Food and Drug Administration Modernization Act of 1997 ("FDAMA"). *Id*. FDAMA amended the FDCA and added Section 503A—creating a federal overlay for the regulation of pharmacies engaged in compounding. *See* 21 U.S.C. § 353a. Section 503A set forth new parameters for compounding including active pharmaceutical ingredients and prescription requirements and included an advertising ban prohibiting compounders from advertising their medications. In 2002, however, the Supreme Court struck down Section 503A's advertising ban, invalidating the statute and returning the regulation of compounding pharmacies to the states. *Western States*, 535 U.S. at 377.

B. <u>Congress Revives Section 503A and Solidifies Personalized Care Parameters.</u>

In 2013, Congress passed the Drug Quality and Security Act ("DQSA"), "which, among other things, severed the unconstitutional advertising provisions from Section 503A" and revived the remainder of the statute. *Wellness Pharm., Inc. v. Becerra*, No. 20-3082, 2021 U.S. Dist. LEXIS 179276, *11–12 (D.D.C. Sept. 21, 2021). In place of the unconstitutional advertising ban, DQSA amended the FDCA to include a prohibition against "the advertising or promotion of a compounded drug [if it] is false or misleading in any particular." 21 U.S.C. § 352(bb). From DQSA's passage through to today, FDA has not promulgated any regulations or provided any guidance under this Section to create the parameters for advertising compounded drugs.

In passing the DQSA, Congress's intent was to maintain patient access to quality compounded medications filling a critical role in personalized patient care. *See, e.g.*, 159 CONG. REC. S8071 (daily ed. Nov. 18, 2013) (statement of Sen. Alexander) ("I want to make clear that all involved on this legislation have no intent of limiting patient or provider access to quality compounded drugs that fill a clinical need"); *see id*. (statement of Sen. Harkin) ("We have worked very hard to craft a proposal that preserves patient access to clinically necessary medications while helping to ensure that providers have access to safe sources of compounded drugs"). Thus, DQSA's purpose in reviving Section 503A was to provide uniformity in the regulation of compounders and avoid the prior piecemeal approach to regulation—while maintaining continued access for physicians to provide personalized care by prescribing compounded medications after determining that manufactured drugs are inappropriate for the patient's care.

To preserve access to compounded medications for personalized patient care, Section 503A exempts compounded drugs from the new drug approval process including clinical trials because "[r]equiring FDA approval of all [compounded] drug products … would, as a practical matter, eliminate the practice of compounding." *Western States*, 535 U.S. at 369. As such, Section 503A draws the line between personalized medication and manufactured one-size-fits-all drugs. *Id*. Congress did so by tying pharmacy compounding to a patient-specific prescription. 21 U.S.C. § 353a(a)(2)(A)–(B). But Section 503A does not require that a pharmacy compound a single prescription's worth of a medication at a time. Rather, Section 503A authorizes compounders to assess patient need based on prescription history and create batches of compounded medications on this basis. *See id*.; *see also* FDA, *Guidance for Industry: Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act*, 5 (Dec. 2016) ("[Section 503A's prescription requirements] are meant to help ensure that compounding … is based on individual

patient needs, and that entities purportedly operating under Section 503A are not actually operating as conventional manufacturers.").[4]

C. Compounding Is Heavily Regulated By States and FDA.

Contrary to how Lilly's Complaint describes the oversight of compounding, an extensive state and federal patient-safety-oriented regulatory framework exists for pharmacies making compounded medications. On a state level, all fifty states impose licensing and regulatory requirements on compounders. These regulatory requirements can vary significantly between states, and the state standards to which compounders are held have evolved over time. The state in which the pharmacy is located and the state(s) into which the pharmacy ships its medications both oversee and inspect compounding pharmacies.

Further, FDA uses its normal process to oversee and inspect compounding pharmacies. Just like with drug manufacturers (such as Lilly), FDA issues a Form 483 subsequent to inspections, setting forth the FDA inspector's compliance observations.[5] These observations are not FDA's final determination regarding compliance, but an interim step in the regulatory process. Like Form 483s, FDA Warning Letters are another advisory tool that are not FDA's final compliance determinations.[6]

D. Compounders Perform Their FDCA-Designated Roles.

In 2022 and 2023, FDA approved Lilly's tirzepatide-based medications Mounjaro® and

[4] *See infra* at 12 n.12 for a discussion regarding the permissibility of taking judicial notice of FDA materials in considering a Rule 12(b)(6) motion.
[5] *See* FDA, *FDA Form 483 Frequently Asked Questions*, www.fda.gov (Jan. 09, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions.
[6] FDA, REGULATORY PROCEDURES MANUAL § 4-1-1 (Mar. 2010) ("[A] Warning Letter is informal and advisory …. FDA does not consider Warning Letters to be final agency action on which it can be sued").

Zepbound®, respectively.[7] Immediately following FDA's approval, FDA placed Lilly's drugs on the shortage list because Lilly could not keep up with patient need.[8] Indeed, for nearly two years, FDA determined that Lilly failed to meet patient need for its drugs. During Lilly's drug shortage, Empower and other compounders dutifully stepped into their FDCA-designated roles, compounding these medications to fill the treatment gap created by Lilly's drug shortage. Because drugs listed on FDA's drug shortage list are not considered "commercially available," compounders can make drugs that are exact copies of manufactured drugs during a drug shortage without violating the FDCA's prohibition against copying commercially available drug products. *See* 21 U.S.C. § 353a(b)(1)(D); *see also* 21 U.S.C. § 353a(d)(1)(B) (indicating that a compounded medication is not an essential copy if the approved drug is on FDA's shortage list).[9]

Once a drug is removed from FDA's shortage list, contrary to Lilly's position, compounding pharmacies, like Empower's pharmacy, may still compound variations of the drug to meet specific patients' needs. FDA has set forth the parameters for this type of compounding in its essential copies guidance.[10] Therein, FDA gives extensive guidance regarding the variations that compounding pharmacies may make. For example, FDA recognizes that compounders may make the very modifications that Lilly is complaining about—altering the route of administration

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[7] *See Application No. 215866 (Mounjaro®)*, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm; Application No. 217806 (*Zepbound®*), Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm.

[8] *FDA Drug Shortages*, Drug Databases, https://dps.fda.gov/drugshortages.

[9] See FDA, *Guidance for Industry: Compounded Drugs that Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act*, p. 5 (Jan. 2018) (indicating that drug products are not commercially available if they are on FDA's Drug Shortage List).

[10] *Id*.

(i.e., injectable to oral) or adding active ingredients or excipients.[11] As with all compounded medications made by pharmacies, a physician must determine that the medication is necessary for the patient by issuing a prescription.

III. LILLY'S COMPLAINT: A THINLY-VEILED ATTEMPT TO ELIMINATE COMPOUNDING WITH TIRZEPATIDE

Under the guise of false advertising and patient safety, Lilly's Complaint sets forth three core theories against Empower arising from Empower's tirzepatide ODT and tirzepatide/niacinamide medications, as well as Empower's indication that it is regulatorily compliant. Compl. ¶ 40. Lilly's theories are as follows:

Safety and Effectiveness Theory: Lilly alleges that Empower's reference to and summarization of articles describing the clinical data surrounding tirzepatide, the active pharmaceutical ingredient, falsely promises that "untested and unapproved Empower oral disintegrating tablets and tirzepatide/niacinamide injections are safe and effective in treating diabetes and addressing chronic weight management." Compl. ¶ 83. The Complaint alleges that Empower made the following statements about tirzepatide, the active pharmaceutical ingredient:

- "play[s] a role in blood sugar regulation," "contribute[s] to a decreased appetite," "support[s] the body's natural metabolic process" and even "influence[s] fat metabolism." Compl. ¶ 44.
- "decreases hemoglobin A1C levels more effectively than a placebo" and "SURPASS-5 clinical trial revealed a -2.11% drop in hemoglobin A1C levels at per 5mg per week dose." Compl. ¶ 49.
- can be "implemented as a second-line defense against type 2 diabetes for glycemic control," "significantly reduce[] bodyweight," and "help people with non-alcoholic fatty liver disease." Compl. ¶ 51.

These statements are false, states Lilly, because the referenced data is based on injectable tirzepatide, and "there are material differences in bioavailability between an oral product and a subcutaneous injection." Compl. ¶ 43. Further, because "Lilly's clinical study provides data on

[11] *Id.*

the safety and effectiveness of Lilly's injectable tirzepatide, administered at Lilly's approved dosages—it says nothing about whether tirzepatide combined with niacinamide is safe and effective for any indicated use in humans." Compl. ¶ 50.

Personalization Theory: Lilly alleges that because Empower advertises certain doses and specific medications that Empower's claims that its products are "custom-made, personalized products" are false. Compl. ¶ 54 (internal quotations omitted). Specifically, Lilly alleges:

- "On its website, Empower sells a single Tirzepatide ODT product at fixed dosages. Contrary to its claims of personalization, Empower's website does not offer any opportunity to select additives or adjust dosage to fit a patient's specific needs." Compl. ¶ 59.
- "Empower offers a single combination of tirzepatide and niacinamide at fixed dosages. Again, Empower's website offers no opportunity to select a different additive or adjust dosage to fit a patient's specific needs." Compl. ¶ 60.

Thus, according to Lilly, "Empower's practice of selling its Tirzepatide ODT and combination tirzepatide injectable as "personalized" products is deceptive, because in fact, Empower is mass manufacturing, one-size-fits-all drugs." Compl. ¶ 62.

Compliance Theory: Based on non-final observations by FDA and state matters resolving conduct that far pre-date Empower's advertisements at issue, Lilly asserts that Empower's current statements that it "adheres to regulatory requirements and maintains high-quality standards, when it does not" are false. Compl. ¶ 40. In support of its assertion, Lilly cites the following: a 2015 FDA Form 483, a 2017 FDA Warning Letter, a 2019 FDA Form 483, a 2020 FDA Form 483, a 2021 FDA Warning Letter, a 2022 FDA Form 483, a 2023 FDA Form 483, and a 2024 FDA Form 483, as well as a 2023 Form 483 issued to a separate entity, Compl. ¶¶ 66–73, ¶ 78, and prior settlements with the California, Colorado, Alabama, Florida, and Pennsylvania Boards of Pharmacy. Compl. ¶¶ 74–76.

Based on the Safety and Effectiveness theory and the Personalization theory, Lilly purports to state a claim under NJCFA. Compl. ¶¶ 85–99. Relying on all three theories, Lilly also alleges a claim under the Lanham Act. Compl. ¶¶ 101–108.

IV. LEGAL STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient ***factual matter***, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (*quoting Bell Atlantic v. Twombly*, 550 U.S. 544, 570 (2007)) (emphasis added). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

The court must determine whether the factual allegations in a complaint state a plausible claim for relief based on "judicial experience and common sense." *Id.* at 679. Because a "court is not bound to accept as true a legal conclusion couched as a factual allegation." *G&W Labs., Inc. v. Laser Pharms. LLC*, No. 17-3974, 2018 U.S. Dist. LEXIS 102132, *4 (D.N.J. June 19, 2018) (quoting *Papasan v. Allain*, 478 U.S. 265, 286 (1986) (internal citations omitted). The complaint must contain more than "just conclusory statements or a recitation of the elements of the cause of action." *G&W Labs*, 2018 U.S. Dist. LEXIS 102132, *18 (quoting *Twombly*, 550 U.S. at 556). Thus, when reviewing a motion to dismiss for failure to state a claim under Rule 12(b)(6), a court must "determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *FTC v. AbbVie Inc.*, 976 F.3d 327, 351 (3d Cir. 2020) (citation and quotations omitted).

As a general rule, a court deciding a motion to dismiss "may not consider matter extraneous to the pleadings." *In re Rockefeller Ctr. Props. Sec. Litig.*, 184 F.3d 280, 292 (3d Cir. 1999). But there are "exceptions to this general rule." *Id*. "A document integral to or explicitly relied upon in the complaint may be considered without converting the motion [to dismiss] into one for summary judgment." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d. Cir. 1997) (internal quotations omitted). Similarly, matters of public record such as a "letter decision of government

agencies and published reports of administrative bodies" may also be considered. *In re Rockefeller Ctr. Props. Sec. Litig*., 184 F.3d at 293 (quoting *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196–97 (3d Cir. 1993)).[12] Here, the court can consider Empower's statements, both referenced in and appended to Plaintiff's Complaint, in evaluating whether Plaintiff's Complaint meets the appropriate pleading standards. the Court may also consider documents from the FDA.

V. ARGUMENT

A. Plaintiff Lacks Standing To Assert A NJCFA Claim.

The New Jersey Consumer Fraud Act is—by its title and express terms—a *consumer* protection statute. As a *consumer* protection statute, the NJCFA "provides relief to *consumers* from 'fraudulent practices in the market place.'" *Lee v. Carter-Reed Co. LLC*, 203 N.J. 496, 521, 4 A.3d 561 (2010) (quoting *Furst v. Einstein Moomjy, Inc*., 182 N.J. 1, 11, 860 A.2d 435 (2004) (emphasis added). To establish a cause of action under the NJCFA, a consumer must plead "(1) an unlawful practice, (2) an ascertainable loss, and (3) a causal relationship between the unlawful conduct and the ascertainable loss." *Gonzalez v. Wilshire Credit Corp.,* 207 N.J. 557, 576, 25 A.3d 1103 (2011). Because the NJCFA is a consumer protection statute, a corporate/entity plaintiff lacks standing to pursue their claim under NJCFA, unless it can point to a "consumer-like injury." *See Church & Dwight Co. v. SPD Swiss Precision Diagnostics*, No. 10-453, 2010 U.S. Dist. LEXIS 133114, *30–31 (D.N.J. Dec. 16, 2010). Put another way, the NJCFA cannot be used to redress

[12] Courts may take judicial notice of FDA public records. *Spizzirri v. Zyla Life Scis.*, 802 F. App'x 738, 739 (3d Cir. 2020) (district court did not abuse discretion in taking judicial notice of an FDA memorandum published on FDA's website); *Otsuka Pharm. Co., Ltd. v. Torrent Pharms. Ltd., Inc.*, 118 F. Supp. 3d 646, 655 n.7 (D.N.J. 2015) ("In deciding the pending motion to dismiss, the Court may take judicial notice of public records or documents of the FDA relating to the issue in this litigation.") (cleaned up); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 754 n.2 (E.D. Pa. 2003) (taking judicial notice of a published report available on FDA's website).

alleged commercial competitor harms—precisely the prohibited redress Lilly seeks here.

It is well-established that the NJCFA does not provide relief for a *competitor* who asserts, as Lilly does, that it was harmed by the acts of another competitor. *See e.g.*, *Church & Dwight Co.*, 2010 U.S. Dist. LEXIS 133114, *30–31 (D.N.J. Dec. 16, 2010) (holding that "the NJCFA was enacted to protect consumers; although this protection has been extended to businesses acting as consumers, the NJCFA was not enacted to redress business disputes"); *Interlink Prods. Int'l, Inc. v. F & W Trading LLC*, No. 15-1340, 2016 U.S. Dist. LEXIS 44256, *28–29 (D.N.J. Mar. 31, 2016) (dismissing plaintiff's claims against a competitor because plaintiff had not suffered a "consumer-like injury"); *Sanofi-Aventis U.S. LLC v. Novo Nordisk, Inc.*, No. 16-9466, 2017 U.S. Dist. LEXIS 106008, *2 (D.N.J. July 10, 2017) (dismissing plaintiff's NJCFA claim because "plaintiff is a competitor, and does not allege a consumer-like injury"); *Natreon, Inc. v. Ixoreal Biomed, Inc.*, No. 16-4735, 2017 U.S. Dist. LEXIS 114598, *18 (D.N.J. July 21, 2017) (dismissing a counterclaim based on the NJCFA because there was no "consumer-oriented transaction" giving way to a "consumer-like injury").

Here, Plaintiff has alleged the exact type of competitive injuries that this Court has repeatedly found are not actionable under the NJCFA. Plaintiff alleges that "Empower's deceptive and unlawful conduct is interfering with Lilly's ability to ***conduct its business***." Compl. ¶¶ 91, 97 (emphasis added). Plaintiff goes on to explain that it "has suffered and will continue to suffer … discernible ***competitive injury*** by the loss of goodwill." Compl. ¶¶ 92, 98 (emphasis added). This Court has held—time and again—that competitive injuries such as these are not the type of losses for which NJCFA provides relief. Plaintiff has not—and cannot—allege any facts that authorize Plaintiff to seek relief under the NJCFA because Plaintiff is not—and has never been—a direct purchaser of Empower's medications. In short, the NJCFA was enacted to protect consumers, not

competitors. Lilly is not a consumer or purchaser of goods or services from Empower. As a competitor, Plaintiff lacks standing to bring a CFA claim. Because Plaintiff can never establish a "consumer-like injury" by Empower, Lilly lacks standing to bring a claim under the NJCFA, and both Counts I and II should be dismissed with prejudice.

B. Plaintiff Fails To State A Claim Under The Lanham Act.

A plaintiff who asserts a claim under the Lanham Act must establish that: (1) the defendant made a false or misleading description of fact or representation of fact in a commercial advertisement about his own or another's product; (2) the misrepresentation is material, in that it is likely to influence the purchasing decision; (3) the misrepresentation actually deceives or has the tendency to deceive a substantial segment of its audience; (4) the defendant placed the false or misleading statement in interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with its products. *See Pernod Ricard USA, LLC v. Bacardi U.S.A., Inc.*, 653 F.3d 241, 248 (3d Cir. 2011).

The Lanham Act distinguishes between literally false ads and those which, while true, are misleading in context. *Highmark, Inc. v. UPMCHealth Plan*, 276 F.3d 160, 171 (3d Cir. 2001). "In analyzing whether an advertisement or product name is literally false, a court must determine, first, the unambiguous claims made by the advertisement or product name, and second, whether those claims are false." *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 586 (3d Cir. 2002) (quoting *Clorox Co. P.R. v. Proctor & Gamble Com. Co.*, 228 F.3d 24, 35 (1st Cir. 2000)). In the absence of literal falsity, the burden is on the plaintiff to show that the advertisement's intended audience was, in fact, left with a false impression. *See KDH Elec. Sys. Inc. v. Curtis Tech, Ltd.*, 826 F. Supp. 2d 782, 806 (E.D. Pa. 2011) (dismissing a claim where the plaintiff merely plead that customers "may be misled" and not that

customers were "actually misled") (citing *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 228–29 (3d Cir. 1990)).

The Lanham Act also only provides relief for false or misleading representations of ***fact***. Statements of opinion or "puffery" are not actionable. *See Intermountain Stroke Ctr., Inc. v. Intermountain Health Care, Inc*., 638 F. App'x 778, 786 (10th Cir. 2016) ("Essential to any [Lanham Act] claim is a determination of whether the challenged statement is one of fact—actionable under [the Lanham Act]—or one of general opinion—not actionable under [Lanham Act]."") (quoting *Pizza Hut, Inc. v. Papa John's Int'l, Inc.*, 227 F.3d 489, 495–96 (5th Cir. 2000)). When a statement constitutes non-actionable puffery, the Court may dismiss the claim at the 12(b)(6) stage. *Ezaki Glico Kabushiki Kaisha v. Lotte Int'l Am. Corp.*, 2016 U.S. Dist. LEXIS 185577, *5 (D.N.J. Dec. 13, 2016) ("Whether a statement in an advertisement is 'puffing' within the meaning of the Lanham Act may be decided on a motion to dismiss."); *see also Graco Inc. v. PMC Global Inc.*, No. 08-1304, 2012 U.S. Dist. LEXIS 188865, *47 (D.N.J. Feb. 15, 2012) ("Whether a statement qualifies as puffery can be decided as a matter of law.").

Further, it is well-established that the FDCA contains no private right of action; only the FDA may bring actions to enforce or restrain alleged violations of the FDCA. *See* 21 U.S.C. § 337(a) (instructing that "all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States.") Therefore, a Lanham Act claim is precluded where its adjudication would "directly conflict[] with [FDA]'s policy choice" or otherwise "undermin[e] [FDA's] judgment." *Pom Wonderful, LLC v. Coca-Cola Co*., 573 U.S. 102, 120 (2014). "[W]hat the [FDCA] … do[es] not create directly, the Lanham Act does not create indirectly, at least not in cases requiring original interpretation of th[is] Act [ ] or [its] accompanying regulations." *Sandoz*, 902 F.2d at 231.

Courts have recognized that Lanham Act claims are precluded where plaintiff's factual allegations require FDA's "particular expertise" to resolve. *See Allergan USA Inc. v. Imprimis Pharm., Inc.*, No. 17-1551, 2018 U.S. Dist. LEXIS 226392, *21 (C.D. Cal. Apr. 30, 2018) ("[C]laims regarding compliance with federal and state regulations dealing with requirements 'as to safety and … identity and strength, and … quality and purity characteristics' as well as contamination, quality control, sterility, and testing are likely precluded by the FDCA … Lanham Act claims that require [ ] FDA's particular expertise or rulemaking authority are precluded."). In other words, courts readily find FDCA preclusion when a plaintiff's Lanham Act claim cannot be resolved through simple binary factual determinations. *See id.* *7 ("[C]laims that directly implicate [ ] FDA's rulemaking authority, are not binary factual determinations, or involve an issue on which [ ] FDA has taken positive regulatory action are all likely precluded by [ ] FDA."); *see also Azurity Pharms., Inc. v. Edge Pharma, LLC*, 45 F.4th 479, 501 (1st Cir. 2022) (finding Lanham Act claims were not precluded because the claim in that case merely required the court make a binary determination as to "whether a particular drug appears" on one of two published lists, and therefore no FDA expertise was implicated).

1. Plaintiff's Safety and Effectiveness Theory Does Not Provide a Basis for Relief Under the Lanham Act.

Lilly's problem with Empower is not about Empower's statements. Rather, Plaintiff's problem is that Empower continues to utilize tirzepatide post-shortage to compound medications to address patient-specific needs, as authorized by the FDCA and FDA. Lilly is arguing with the federal regulatory scheme that authorizes Empower to use active pharmaceutical ingredients, like tirzepatide, that are a "component of a drug approved by [FDA]." 21 U.S.C. § 353a(b)(1)(A)(i)(II). As such, Empower can compound with tirzepatide and Empower is authorized to advertise its compounded medications, including those made using tirzepatide. *See Western States*, 535 U.S. at

377 (invalidating the advertising ban on compounded medications as unconstitutional).

Because there is nothing wrong with what Empower is doing—and Empower can advertise what it is doing—there is nothing false or misleading about Empower's advertisements. Empower's citations to studies about tirzepatide and statements about oral formulations are not literally false; because there is no literal falsity, Lilly is required to identify consumer confusion, but has failed to do so; FDA's expertise is needed to evaluate Empower's study citations and oral formulation statements for scientific accuracy; and Empower's oral formulation statements about functionality and ease of use are opinions and puffery. For these reasons, Lilly's Safety and Effectiveness theory fails.

i. Empower's Citations to Studies About Tirzepatide and Statements About Oral Formulation's Convenience Are Not Literally False.

Plaintiff claims that Empower's Product Overview page for tirzepatide/niacinamide and tirzepatide ODT are false advertisements because Empower cites to and summarizes articles discussing tirzepatide, the active pharmaceutical ingredient in Lilly's manufactured drug, and separately cites to and summarizes articles discussing niacinamide, the other active pharmaceutical ingredient in Empower's compounded tirzepatide. Compl. ¶¶ 42–53; Exhibit 1 – Empower's Product Overview Page for tirzepatide/niacinamide; Exhibit 2 – Empower's Product Overview Page for tirzepatide ODT; *see supra* at 12 n.12 (judicial notice). Plaintiff alleges that Empower's reliance on these articles falsely communicates that Empower's compounded medications have been tested and proven to function as advertised. Compl. ¶¶ 42–53.

Plaintiff conveniently leaves out necessary context for Empower's Product Overview statements that demonstrate that the statements are not literally false on their face. *See Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 946 (3d Cir. 1993) ("In determining facial falsity, the court must view the face of the statement in its entirety, rather than examining the eyes, nose, and mouth

separately and in isolation from each other") (quoting *Cuisinart, Inc. v. Robot-Coupe International Corp.*, No. 81 CIV 731 (CSH) (S.D.N.Y. June 9, 1982)); *see also Johnson & Johnson-Merck Consumer Pharms. Co. v. Rhone-Poulenc Rorer Pharms., Inc.*, 19 F.3d 125, 129 (3d Cir. 1994) ("A determination of literal falsity rests on an analysis of the message in context."). Specifically, Empower's cited studies are clearly and explicitly discussing tirzepatide and niacinamide alone—not Empower's combined tirzepatide/niacinamide or Empower's oral formulation. Empower's citations explicitly reference clinical studies in various medical journals of tirzepatide, alone, and niacinamide, alone. Empower never states nor implies that it hosted, conducted, funded, or developed the cited data—in fact, Empower includes citations showing the source of this data, demonstrating to consumers that this data is not Empower's own data.

Further, Plaintiff alleges that the following generalized convenience statements are false: "No needles, no refrigeration, no preparation," and "Skip the needle and get customized weight management support with the new tirzepatide ODT." Compl. ¶¶ 46–48. However, again, Empower's statements are literally true—Empower's oral formulation does not require needles, refrigeration or preparation and allows patients to skip the needles and receive customized weight management support with the compounded medication.

Therefore, Lilly fails to allege how Empower's citations to studies about tirzepatide and statements about the oral formulation's convenience are literally false.

ii. Because Empower's Study Citations and Oral Formulation Statements Are Not Literally False, Lilly Is Required to Identify Consumer Confusion, But Has Failed to Do So.

Since Empower's statements are not false on their face, as shown above, Lilly is forced to proceed on a theory that Empower's statements, while true, are misleading. Compl. ¶ 49. Stated differently, Lilly asserts that Empower's summarization of the tirzepatide data is true, but allegedly misleading when applied to Empower's compounded medications. Compl. ¶¶ 49–52. Plaintiff,

however, has not pleaded any supporting factual allegations establishing that consumers are "actually" confused or deceived by Empower's website or statements, as required for the "true but misleading" variation of Lanham Act claims. *See Eli Lilly & Co. v. Roussel Corp.*, 23 F. Supp. 2d 460, 475 (D.N.J. 1998) ("A plaintiff can maintain an action under the Lanham Act even 'where the advertisements are not literally false' so long as there is evidence of actual consumer confusion or deception.")

Lilly has failed to adequately allege "how" or "why" Empower's citations to or summaries of data regarding tirzepatide, the active pharmaceutical ingredient, would lead a reasonable consumer into ignoring the plain text of the studies and instead believe that the studies pertain specifically to Empower's compounded medications. Lilly simply asks—without any survey or other credible basis—this Court to assume that the reasonable consumer will automatically make this leap, but courts cannot accept such implausible inferences even at the motion to dismiss stage. *See id.* at 475–80 (reasoning that courts need not make implausible leaps in logic in inferring effects on consumers that are not directly tied to the claimed false statements); *see also FedEx Ground Package Sys., Inc. v. Route Consultant, Inc.*, 97 F.4th 444, 455 (6th Cir. 2024) (explaining that when considering the pleaded facts in a light most favorable to the plaintiff, only "reasonable inferences" are drawn in the plaintiff's favor). Because Lilly has failed to plead any facts establishing consumer confusion from Empower's citations to studies about tirzepatide and oral formulation convenience statements, Plaintiff's claims fail.

iii. FDA's Expertise Is Needed to Evaluate Empower's Study Citations and Oral Formulation Statements for Scientific Accuracy.

Plaintiff claims that Empower's citations to tirzepatide data are inappropriate when applied to Empower's compounded medications because there are differences in the bioavailability between oral and injectable medications, and there are no studies regarding Empower's specific

compounded medication—an oral form of tirzepatide and tirzepatide/niacinamide as an injectable. Compl. ¶¶ 42–43 The FDCA sets forth the active pharmaceutical ingredient requirements for compounders and specifically authorizes compounders to utilize active pharmaceutical ingredients that are "a component of a drug approved by [FDA]." 21 U.S.C. § 353a(A)(b)(1)(A)(i)(II). Accordingly, Empower uses tirzepatide, the active pharmaceutical ingredient in Lilly's manufactured drug, to compound medications following a physician's determination that the medication is necessary for treatment. Plaintiff does not allege that Empower's medications do not contain tirzepatide; nor does Plaintiff allege that Empower's tirzepatide is different than the active pharmaceutical ingredient at issue in the cited articles. Compl. ¶¶ 1–108.

Here, Plaintiff asks this Court to rule on the open-ended question of whether it is appropriate for Empower to reference data about tirzepatide when discussing certain types of tirzepatide-containing compounded medications in its advertising. But, FDA has oversight of compounded drug advertisements. *See* 21 U.S.C. § 352(bb) (prohibiting "the advertising or promotion of a compounded drug [if it] is false or misleading in any particular."). FDA has not promulgated regulations or issued guidance interpreting Section 352(bb)—there is certainly no FDA guidance as to what types of studies compounders can cite in advertisements regarding the active ingredients used in their compounded medications.

Thus, the question of falsity requires an open-ended determination better suited for FDA. FDA must weigh in—and has not—on whether it is scientifically appropriate for Empower to refer data regarding the individual ingredients (tirzepatide and niacinamide) when referencing Empower's combination tirzepatide/niacinamide medication. And, as for Lilly's complaints about Empower's marketing of its oral form of tirzepatide, FDA must weigh in—and has not—on whether there are differences in bioavailability between oral and injectable medications such that

Empower's references to the tirzepatide studies are inappropriate. All these issues are open-ended questions that are squarely in the exclusive province of FDA. *See Allergan U.S. v. Imprimis Pharms., Inc.*, No. 17-1551, 2017 U.S. Dist. LEXIS 223117, *18–20 (C.D. Cal. Nov. 14, 2017) (reasoning that claims that are not binary factual determinations but rather involve open-ended determinations are precluded); *see also G&W Labs.*, 2018 U.S. Dist. LEXIS 102132, *48 ("[C]ourts have refused to allow a Lanham Act claim to proceed where, in order to determine the falsity or misleading nature of the representation at issue, the court would be required to interpret and then apply FDCA statutory or regulatory provisions ….") (quoting *Mut. Pharm. Co. v. Ivax Pharms., Inc.*, 459 F. Supp. 2d. 925, 934 (C.D. Cal. Oct. 17, 2006)). Because Lilly's Lanham Act claim requires nuanced, open-ended determinations by FDA to establish falsity, Plaintiff's claims are precluded and therefore must fail.

iv. Empower's Oral Formulation Statements About Functionality and Ease of Use Are Non-Actionable Opinion and Puffery.

Plaintiff alleges that the following generalized convenience statements are superiority claims: "No needles, no refrigeration, no preparation," "Just an easy, consistent routine," and "Skip the needle and get customized weight management support with the new tirzepatide ODT." Compl. ¶¶ 46–48. According to Plaintiff, the statements communicate that "Tirzepatide ODT is better (i.e., more convenient and less painful) yet just as safe and effective as Lilly's FDA-approved and clinically tested medicines." Compl. ¶ 48.

Empower's oral formulation statements are nothing more than puffery and are akin to the type of statements that courts have found to be non-actionable opinions. *See, e.g.*, *EP Henry Corp. v. Cambridge Pavers, Inc.*, 383 F. Supp. 3d 343, 349–50 (D.N.J. 2019) ("Beauty … to last a lifetime" and "unrivaled beauty" found to be "generalized and vague claims that constitute puffery" and are not actionable); *Pizza Hut*, 227 F.3d at 498 ("Better Pizza, Better Ingredients"

found to be non-actionable puffery); *Intermountain*, 638 F. App'x at 789 (finding defendants statements of "best practices and high-quality care to be merely sales puffery that cannot form the basis of a Lanham Act claim."); *Ezaki Glico Kabushiki Kaisha*, No. 15-5477, 2016 U.S. Dist. LEXIS 185577, *5 (statement that a consumer can "'get a mental boost'" from product "is classic puffery" because "[o]n its face, the statement is general, vague, and non-specific," and thus dismissal at 12(b)(6) stage was warranted).

This Court's reasoning in *EP Henry* is instructive. *EP Henry Corp. v. Cambridge Pavers, Inc.*, No. 17-1538, 2017 U.S. Dist. LEXIS 180802 (D.N.J. Oct. 31, 2017). In *EP Henry*, plaintiff, a concrete paving company, filed suit against a competitor concrete paving company arising from statements that its competitor made about its concrete stones. Defendant moved to dismiss on the basis that the following statements: "AmorTec pavers will 'always look new,'" ArmorTec pavers will 'look like new forever,'" with ArmorTec pavers, 'the color will never fade,'" were non-actionable puffery. *Id*. *3. In isolation, the Court agreed that such statements would be disregarded as "exaggerated boasting or opinions (i.e., puffery)." *Id*. *7.

However, the defendants had gone a step further and paired each exaggerated opinion to its "allegedly breakthrough technology." *Id*. This combination, the Court found, could lead a potential customer to believe that defendant's breakthrough technology actually was the "'secret sauce' to enable pavingstones to 'look like new forever' or ensure that 'the color will never fade.'" *Id*. *8. Here, in contrast, Empower has not taken that further step and included any measurable indicator of the "convenience" of its ODT tirzepatide. Rather, Empower has stated its opinion that oral medications are more convenient and easier to take than injectable medications. This opinion is not an actionable false statement of fact under the Lanham Act.

Therefore, Lilly's Safety and Effectiveness theory fails to state a claim under the Lanham

Act because Empower's citations and statements are literally true, there are no facts pleaded to establish consumer confusion, and the statements are nonactionable puffery. Further, Lilly's claims are precluded because establishing the alleged falsity requires FDA's scientific expertise. Each of Empower's challenges warrants dismissal at the 12(b)(6) stage.

2. Plaintiff's Personalization Theory Contradicts the Federal Regulatory Requirements.

Plaintiff's Personalization theory is a full-blown attack on Section 503A's regulatory framework. According to Lilly, "personalization" means making compounded medications one-by-one after the receipt of a prescription for a specific patient and does not include "predetermined dosages." Compl. ¶ 58. In Lilly's world, Empower's public facing website should include the "opportunity [for patients] to select additives or adjust dosages to meet a patient's specific needs." Compl. ¶ 59. Because Empower's public-facing website does not comport with Lilly's view of personalized medication, Lilly's complaint concludes that there is nothing "personalized" about Empower's compounded medications. Compl. ¶ 62. However, the FDCA and FDA, not Lilly, determine what constitutes "personalized medication."

i. Empower's Personalization Statements Are True Under Section 503A; Therefore, Lilly's Personalization Assertions Are Precluded Because They Directly Contradict the Regulatory Framework.

It is Section 503A and FDA that define what constitutes "personalized" medications. Section 503A ensures compounded medications remain "personalized" by requiring that every compounded medication be tied to a prescription for a specific patient. FDA calls this the prescription requirement. FDA considers the prescription requirement the determining factor in "personalized" care, stating that:

> The prescription requirement under Section 503A is a critical mechanism to distinguish compounding by a licensed pharmacist … from conventional manufacturing, and to ensure that drug products compounded under Section 503A … are provided to a patient only based on individual patient need.

FDA, *Guidance for Industry: Prescription Requirement Under Section 503A of the Federal Food Drug and Cosmetic Act*, 5 (Dec. 2016).

However, Section 503A does not require that a compounder make medications one-by-one. Rather, Lilly's one-by-one compounding limitation contradicts both the FDCA and FDA's published guidance interpreting Section 503A. Section 503A ***explicitly*** authorizes compounders to assess patient needs and create batches of compounded medications for subsequent dispensing. *See* 21 U.S.C. § 353a(a)(2)(A)–(B)(i)(ii)(I)-(II). Under Section 503A, compounding batches of medications is consistent with "personalization" a physician determines that the compounded drug is needed for treatment by writing a prescription. Thus, Empower listing "fixed dosages" on its website is nothing more than publication of Empower's compliance with batch allowances under Section 503A.

Lilly's desire that Empower's public facing website provide patients with the opportunity to "select additives" or "adjust dosages" to fit a patient's specific needs also flies in the face of Section 503A. Compl. ¶¶ 59–60. Section 503A requires a physician to write a prescription to determine what personalization is necessary for a specific patient. No public-facing website available to consumers should allow a patient to self-select medications without consulting a physician. FDA unambiguously states that the prescription requirement is the bedrock of Section 503A.

Plaintiff's claims, therefore, are nothing more than an attempt to rewrite a federal regulatory framework that Lilly does not like. All of Lilly's claims which allegedly demonstrate that Empower falsely represents that its compounded medications are "personalized" are Lilly's fantasy of how limited compounding ***should be*** but is not. Compl. ¶¶ 54–62. Empower is explicitly authorized under Section 503A to compound more than one medication at a time, and patients

should not be allowed to request changes to their medications through a public-facing website without a physician's determination of necessity. Thus, Empower's statements regarding "personalization" are literally true as determined by Section 503A and FDA. Yet, Lilly asks this Court to "directly conflict[] with [FDA]'s policy choice" and otherwise "undermin[e] [FDA's] judgment." *See Pom Wonderful*, 573 U.S. at 120. In the absence of a false statement of fact, Lilly's personalization Lanham Act allegations cannot survive a motion to dismiss.

ii. Because Under Section 503A Empower's Medications Are Personalized, Lilly Must Plead Consumer Confusion, But Has Failed to Do So.

According to Lilly, Empower's classification of its compounded medications as "personalized" is misleading because Empower's website features specified formulations and doses without the option for patient-by-patient modification. Compl. ¶¶ 54–62. Lilly's theory is essentially this: Empower cannot classify its compounded medications as "personalized" and simultaneously feature some of the personalized medications that Empower offers. *Id*. Lilly, however, pleads no facts alleging that consumers hold Lilly's rigid view of "personalization." *Id*. Lilly does not allege that Empower advertises medications that it does not compound, or, that consumers are confused about which personalized medications Empower offers. *Id*. Instead, Lilly acknowledges that Empower specifically advises consumers regarding specific dosages and formulations. Compl. ¶¶ 59–60. Lilly pleads no facts that any consumers thought their medications were not "personalized" because Empower advertised some of the doses and formulations that Empower makes. *See Eli Lilly & Co. v. Roussel*, 23 F. Supp. 2d at 475–80 (reasoning that courts need not make implausible leaps in logic in inferring effects on consumers that are not directly tied to the claimed false statements). Because Lilly has failed to plausibly plead that Empower's website featuring some personalized compounded medications options misleads anyone, Plaintiff's claims fail on their face for not meeting Fed. R. Civ. P. 8(a) pleading standards.

iii. If Lilly's Personalization Theory Is Not Precluded, the Statements Are Non-Actionable Opinion Statements.

Further, if Lilly's personalization allegations are not precluded, Lilly still cannot establish a claim under the Lanham Act because Empower's statements regarding "personalization" are non-actionable opinion statements, and any alleged falsity hinges on regulatory determinations that FDA has not made. *See e.g., Coastal Abstract Service, Inc. v. First Am. Title Ins. Co.*, 173 F.3d 725 (9th Cir. 1999); *Dial A Car, Inc. v. Transp., Inc.*, 82 F.3d 484 (D.C. Cir. 1996).

Lilly's one-by-one compounding limitation, patient additive selection requirement, and aversion to fixed dosages are Lilly's interpretation of "personalized" medicine. But "personalized" medicine for a compounder like Empower is based on Section 503A's prescription requirements. FDA has not determined that Empower's compounding of batches, failure to offer additive options on its public-facing website, or advertising fixed dosages violate any of Section 503A's "personalization" requirements. *See Dial A Car*, 82 F.3d at 489 (requiring an unambiguous clear interpretation from the appropriate regulatory authority at the time the statements were made to establish falsity). Absent such a ruling, Empower's "personalized" medicine statements are "opinion statements, and not statements of facts" actionable under the Lanham Act, *id*., and subject to dismissal.

iv. Alternatively, Empower's "Personalization" Statements Are Non-Actionable Puffery.

If Section 503A's parameters are not the metric for determining personalization for compounded medication, then no metric exists; therefore, Empower's personalization statements are non-actionable puffery. *See Castrol*, 987 F.2d at 945–46 (finding that the difference between actionable and non-action statements is whether the statement can be measured and tested versus a statement that is vague and cannot be empirically tested). Without Section 503A, there is no way for this Court to empirically test "personalization" to establish Empower's statements as those of

objective facts. *See EP Henry*, 383 F. Supp. at 352 (finding statements abouts a product's durability actionable statements of fact because the statements can be objectively tested through analysis of the product); *see also Ezaki Glico Kabushiki Kaisha*, 2016 U.S. Dist. LEXIS 185577, *6 (finding the statement "get a mental boost" from Pocky to be classic puffery because the "statement is general, vague, and non-specific," further reasoning that "[a] 'mental boost' does not imply an improvement in any particular measurable characteristic.")

The Sixth Circuit's reasoning in *FedEx* is persuasive on this point. There, plaintiff brought Lanham Act claims against defendant's statements regarding the alleged "collapsing" of plaintiff's business model, the "soaring" default rate," and plaintiff's alleged "financial distress." *FedEx*, 97 F.4th at 456–57. The Sixth Circuit analyzed each of these statements and found them to be untestable or vague words, reasoning that there was no way to measure or reasonably interpret the statements as objective facts. *Id.* The Sixth Circuit found each statement to be puffery.

Here, the same is true of Empower calling its compounded medications "personalized." There is no way for this Court to empirically test or measure what it means for a drug to be "personalized." Therefore, the personalization statements are non-actionable puffery; as non-actionable puffery, they cannot be used to articulate prong one of a viable Lanham Act claim—a "false statement of fact." As such, Lilly's complaint must be dismissed.

As such, Lilly's Personalization theory fails to state a claim under the Lanham Act because Lilly's claims are precluded as they directly contradict Section 503A's requirements or, in the alternative, Empower's statements are non-actionable opinion statements or puffery. Each of Empower's arguments results in dismissal of Plaintiff's claims under 12(b)(6).

3. Plaintiff's Compliance Theory Depends Upon Regulatory Determinations That Have Never Been Made and Contradict FDA's Regulatory Scheme.

Plaintiff's Compliance theory is based on Lilly's desire to eliminate compounding with

tirzepatide. To do so, Lilly tries to convert FDA's interim findings into final compliance determinations, in direct contravention of FDA's regulatory scheme. Further, Lilly drags irrelevant, prior state actions into this suit to claim that Empower's current statements regarding regulatory compliance are false.

Specifically, Plaintiff's Compliance theory centers on the below:

- "adheres to stringent regulations set by State Boards of Pharmacy, the FDA, and USP standards, and even voluntary quality testing." Compl. ¶ 63.
- "multi-pronged quality process adheres to stringent regulatory standards across every step—from ingredient sourcing to fulfilment [*sic*]—so the medications [it] send[s] out are of the highest caliber every time." Compl. ¶ 63.

i. Lilly's Compliance Theory Is Precluded Because It Contravenes FDA's Regulatory Scheme.

For Plaintiff to establish that Empower's statements supporting Plaintiff's Compliance theory are false, Plaintiff seeks to convert interim, non-final observations from FDA into an unambiguous determination of non-compliance. Compl. ¶¶ 66–73; ¶ 78. This effort is in direct contravention of FDA's policy choice and therefore, these allegations are precluded. *See Pom Wonderful*, 573 U.S. at 120. FDA chooses to use Form 483s and Warning Letters as advisory actions to obtain voluntary compliance. According to FDA, neither a Form 483 nor a Warning Letter is a final determination that a violation of the FDCA has occurred.[13]

Courts in this circuit have followed FDA's lead. *See e.g., In re Mylan N.V. Sec. Litig.*, No. 20-955, 2023 U.S. Dist. LEXIS 88941, *40 (W.D. Pa. May 18, 2023) ("Importantly, a Form 483 is simply interim FDA feedback. The advisory language that accompanies all Forms 483 makes

[13] *See* REGULATORY PROCEDURES MANUAL, *supra* note 6 ("Warning Letter is informal and advisory … FDA does not consider Warning Letters to be final agency action on which it can be sued."); *see also FDA Form 483 Frequently Asked Questions*, *supra* note 5 (indicating that "[t]he FDA Form 483 does not constitute a final Agency determination of whether any condition is in violation of the FD&C Act or any of its relevant regulations").

clear that the forms do not represent the FDA's final word and do not represent a final agency determination regarding … compliance.") (internal citations and quotation marks omitted); *U.S. v. Allgyer*, No.11-02651, 2012 U.S. Dist. LEXIS 13257, *15 n.16 (E.D. Pa. Feb. 3, 2012) ("The FDA frequently sends warning letters as a way to communicate[ ] the agency's position on a matter, but it does not commit FDA to taking enforcement action"). As such, Plaintiff's federal Compliance theory claims must be dismissed based on preclusion.

ii. Lilly's Compliance Theory Fails Because There Were No Clear Determinations From the Appropriate Regulatory Authority At the Time the Statements Were Made To Establish Falsity.

Plaintiff relies on Empower's state settlement agreements involving *old* conduct, asserting that Empower's present-day statement must, therefore, be false based on "its history of past violations *already established*." Compl. ¶¶ 63–81. But none of the cited state matters establish "a clear and unambiguous ruling from a court or agency of competent jurisdiction" about the status of Empower's regulatory compliance during the relevant time period. *See e.g., Dial A Car*, 82 F.3d at 489 (D.C. Cir. 1996) (requiring an unambiguous clear interpretation from the appropriate regulatory authority at the time the statements were made to establish falsity). Absent such a ruling, Empower's purported compliance statements are non-actionable "opinion statements." *Id*.

In *Dial A Car*, a private car company sued a number of cab companies under the Lanham Act, alleging that the cab companies made false and misleading statements by advertising they were "lawfully" (by local rule) able to offer customers the same corporate services the private car company plaintiff provided, using the cab driver defendants' regular taxicabs. *Dial A Car, Inc. v. Transp., Inc.*, 884 F. Supp. 584, 591–92 (D.D.C. 1995). The cabs argued the statements were not misrepresentations because they were opinions about their services' legality, and the accuracy of their statements were the purview of the local taxi commission's interpretation of DC regulations –and the taxi commission had not published any interpretation. *Id.* at 592. Agreeing, the court

dismissed the Lanham Act count, finding "[t]he only way for the Court to determine whether [defendant's challenged conduct] is illegal is by interpreting regulations that are within the Taxicab Commission's bailiwick." *Id.* In the absence of any taxi commission guidance, it was "generally inappropriate for a court in a Lanham Act case to determine preemptively how an administrative agency will interpret and enforce its own regulations and thereby to usurp the agency's responsibility for interpreting and enforcing potentially ambiguous regulations." *Id.* at 593. Affirming, the D.C. Circuit went even further—even if the taxi commission *subsequently* issued a clear statement of interpretation regarding whether the cab drivers could offer corporate services, it *still* would not be the federal court's place to subject the cab drivers' statements prior to the commission's interpretation to a Lanham Act claim. 82 F.3d at 488–89. The "proper inquiry" was whether, at the time that the cab drivers made their statements, was there an unambiguous clear interpretation from the taxi commission that those statements were false. *Id.* at 489.

Here, Plaintiff has not pled a single, verifiably false statement of fact regarding Empower's compliance with regulatory requirements at the time the alleged compliance statements were made. Rather, Plaintiff claims nothing more than that, at certain times in the past, ***prior to*** the compliance statements of which Plaintiff's complains, Empower entered into settlements with various state boards of pharmacy. Plaintiff's position—that these older matters demonstrate "non-compliance" in perpetuity, barring Empower from ever holding the opinion that it is regulatorily compliant—is implausible. *See Coastal*, 173 F.3d at 731 (discussing that regulatory compliance statements are nothing more than opinion statements). Because Empower's statements are non-actionable opinions, Lilly's Compliance theory based on state settlements fails.

VI. CONCLUSION

For the foregoing reasons, this Court should grant this Motion to Dismiss, and dismiss Plaintiff's Complaint with prejudice.

Dated: June 5, 2025

s/ Stephen M. Orlofsky

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